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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,158	10/03/2003	Thomas A. Russell	50642/287729	3951
30559	7590	08/04/2009		
DIANA HOUSTON SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			EXAMINER ROY, BAISAKHI	
			ART UNIT	PAPER NUMBER
			3737	
			MAIL DATE	DELIVERY MODE
			08/04/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/679,158

**Applicant(s)**

RUSSELL ET AL.

**Examiner**

BAISAKHI ROY

**Art Unit**

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-12 and 19-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-18 and 26-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

2/09, 7/08, 4/08, 12/07, 10/07, 8/07, 5/07, 4/07, 4/07, 1/07, 10/06, 4/06, 12/05, 9/05, 8/04



**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 13-18 and 26-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heilbrun et al. (6491702) in view of Foley et al. (6226548). Heilbrun et al. disclose a method for performing a surgical procedure on an individual's bony anatomy by positioning a platform or plate 314 in contact with an individual's skin such that at least points or part of the plate is in contact with the patient's skin. The plate or platform is used to support items used during surgical procedures such as modular fiducial rods 360 each having upper and lower ends 310, 320. Eight fiducial points 361-368 are formed as balls on rods 360 and each of the rods are fixed at the lower end 310 to plate 314 or platform (fig. 3). The fiducial points represented by the ball/rod combination make up the modular fiducials (col. 9 lines 24-30). Therefore Heilbrun et al. teach the use of multiple modular fiducials or fiducial rods 360 biased on the plate or platform against the skin of the patient. The fiducials are arranged in a pattern which is recognizable or identified by a tracking system such that the tracking system can track and register the position and orientation of the pattern (col. 7 lines 48-59). Heilbrun et al. also teach the use of additional fiducials beyond the 6 required and the extra fiducial

points 367, 368 serve to verify the location coordinates (col. 10 lines 6-10). Therefore the tracking system is used to position the implant relative to the individual.

Heilbrun et al. teach attaching the plate or platform to the patient's skin and would therefore it is obvious that the system would require a fastener of some type but do not explicitly teach such a fastener. In the same field of endeavor Foley et al. disclose an implant for an orthopedic surgical procedure where the orthopedic implant includes a bone clamp 30 attached to the spinous process. Attached to the clamp is a superstructure 20 which includes a central post 150 and the post is inserted in a single orientation and includes fasteners such as screw 43 and the fastener further includes a retainer such as a K-wire and fixed to the screw (fig. 5, 6). The retainer helps the fastener from rotating in either direction when inserted into the spinal element 100 (col. 7 lines 59-col. 8 line 3). Therefore the clamp 30, screw 42, and K-wire 45 are implanted in the skin and attached to the spinal process. The central post 150 is then fixed to the clamp or screw and fiducial array 170 is fixed to the central post. As shown in figures 12 and 13, multiple locations along the spinous process include the use of multiple screws for each individual implant. Therefore it is obvious that multiple fasteners or screws may be used to position implants along different parts of the spinous process depending on the need for such surgical repair. The screw heads 255 (in this embodiment) can be rotatably manipulated under patient's skin (col. 10 lines 57-60). This therefore suggests that the fasteners or screws in this embodiment may be rotated towards each other and also converging towards another screw to ensure proper orientation of the fasteners under the skin. It would have therefore been obvious to one

of ordinary skill in the art to use the teaching by Foley et al. to modify Heilbrun et al. such that the plate or platform is held secured in place to the patient's skin (col. 8 lines 10-27).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Baisakhi Roy/

Examiner, Art Unit 3737